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Claims:

1. (previously presented):A modified release dosage form comprising of a high solubility active ingredient prepared by using dual retard technique to control the release of the high solubility active ingredient, said dosage form comprising a) micro matrix particles containing active ingredient(s) and one or more hydrophobic release controlling agent and b) coating of one or more hydrophobic release controlling agent on said micro matrix particles.

2. (original):A dosage form as claimed in claim 1, is in the form of tablet.

3. (original):A dosage form according to claim 1, wherein the hydrophobic release controlling agents are selected from the group comprising of ammonio methacrylate copolymers type A and B as described in USP, methacrylic acid copolymer type A, B and C as described in USP, polyacrylate dispersion 30% as described in Ph. Eur., polyvinyl acetate dispersion, ethylcellulose, cellulose acetate, cellulose propionate (lower, medium or higher molecular weight), cellulose acetate propionate, cellulose acetate butyrate, cellulose acetate phthalate, cellulose triacetate, poly(methyl methacrylate), poly(ethyl methacrylate), poly(butyl methacrylate), poly(isobutyl methacrylate), poly (hexyl methacrylate), poly(isodecyl methacrylate), poly (lauryl methacrylate), poly(phenyl methacrylate), poly (methyl acrylate), poly (isopropyl acrylate), poly (isobutyl actylate), poly (octadecyl acrylate), waxes such as beeswax, carnauba wax, microcrystalline

wax, and ozokerite; fatty alcohols such as cetostearyl alcohol, stearyl alcohol; cetyl alcohol and myristyl alcohol; and fatty acid esters such as glyceryl monostearate; glycerol monooleate, acetylated monoglycerides, tristearin, tripalmitin, cetyl esters wax, glyceryl palmitostearate, glyceryl behenate and hydrogenated castor oil.

4. (original):A dosage form according to claim 3, wherein said hydrophobic release controlling agents are selected preferably from ammonio methacrylate co-polymers.

5. (original):A dosage form according to claim 4, wherein preferred ammonio methacrylate co-polymers are selected from Eudragit RS (Ammonio Methacrylate Copolymer type B USP), Eudragit RL (Ammonio Methacrylate Copolymer type A USP) and Eudragit NE30D (Polyacrylate dispersion 30% Ph. Eur.).

6. (original):A dosage form according to claim 1,wherein in micro matrix particles, the active ingredient and one or more hydrophobic release controlling agents are present in a ratio of from 100:1 to 100:75.

7. (original):A dosage form according to claim 6,wherein in micro matrix particles, the active ingredient and one or more hydrophobic release controlling agents

are present preferably in a ratio of from 100:2.5 to 100:50.

8. (original):A dosage form according to claim 6,wherein in micro matrix particles, the active ingredient and one or more hydrophobic release controlling agents are present more preferably in a ratio of from 100:2.5 to 100:30.

9. (original):A dosage form according to claim 6,wherein in micro matrix particles, the active ingredient and one or more hydrophobic release controlling agents are present most preferably in a ratio of from 100:2.5 to 100:20.

10. (original):A dosage form according to claim 6 to 9, wherein in micro matrix particles, the active ingredient can be less than or equal to 1500mg.

11. (original):A dosage form according to claim 1, wherein the hydrophobic release controlling agents employed for coating the said micromatrix particles are selected from the group comprising of ammonio methacrylate copolymers type A and B as described in USP, methacrylic acid copolymer type A, B and C as described in USP, polyacrylate dispersion 30% as described in Ph. Eur., polyvinyl acetate dispersion, ethylcellulose, cellulose acetate, cellulose propionate (lower, medium or higher molecular weight), cellulose acetate propionate, cellulose acetate butyrate, cellulose acetate phthalate, cellulose triacetate, poly(methyl methacrylate),

poly(ethyl methacrylate), poly(butyl methacrylate), poly(isobutyl methacrylate), poly (hexyl methacrylate), poly(isodecyl methacrylate), poly (lauryl methacrylate), poly(phenyl methacrylate), poly (methyl acrylate), poly (isopropyl acrylate), poly (isobutyl actylate), poly (octadecyl acrylate), waxes such as beeswax, carnauba wax, microcrystalline wax, and ozokerite; fatty alcohols such as cetostearyl alcohol, stearyl alcohol; cetyl alcohol and myristyl alcohol; and fatty acid esters such as glyceryl monostearate; glycerol monooleate, acetylated monoglycerides, tristearin, tripalmitin, cetyl esters wax, glyceryl palmitostearate, glyceryl behenate and hydrogenated castor oil.

12. (original):A dosage form according to claim 11, wherein the hydrophobic release controlling agents is selected from fatty acid esters.

13. (original):A dosage form according to claim 12, wherein the hydrophobic release controlling agents are selected from the group comprising of hydrogenated castor oil and glycerol distearate.

14. (original):A dosage form according to claim 1, micro matrix particles and coating of one or more hydrophobic release controlling agents are present in a ratio of from 100:0.5 to 100:75.

15. (original):A dosage form according to claim 14, wherein micro matrix particles and coating of one or

more hydrophobic release controlling agents are preferably present in a ratio of from 100:1 to 100:50.

16. (original):A dosage form according to claim 14, wherein micro matrix particles and coating of one or more hydrophobic release controlling agents are more preferably present in a ratio of from 100:2.5 to 100:20.
17. (original):A dosage form according to claim 1, wherein the high solubility active ingredient is selected from the group comprising of antidiabetic agents, anti-histamines, anti-depressants, anti-viral agents, anesthetics, antacids, anti-arththriics, antibiotics, anti-psychotics, anti-spasmodics, anxiolytic agents, appetite suppressants, cardiovascular agents, cough suppressants, emollients, gastro-intestinal agents, growth regulators, respiratory stimulants, vitamins, angiotensin converting enzyme inhibitors, anti-asthmatics, anti-cholesterolemics, anti-convulsants, anti-depressants, anti-diarrhea preparations, anti-infective, anti-inflammatory agents, anti-nauseants, anti-stroke agents, anti-tumor drugs, anti-tussives, anti-uricemic drugs, amino-acid preparations, antiemetics, antiobesity drugs, antiparasitics, antipyretics, appetite stimulants, celebral dilators, chelating agents, cholecystokinin antagonists, cognition activators, deodorants, dermatological agents, diuretics, erythropoietic drugs, fertility agents, synthetic hormones, laxatives, mineral supplements, neuroleptics, neuromuscular agents, peripheral vaso-dilators, prostaglandins, vaginal preparations, vaso-constrictors, vertigo agents, biguanides, sulphonylurease, meglitinides, PPAR gama agonist

[insulin sensitisers (thiazolidinedione)] alpha-glucosidase inhibitors and the like.

18. (original):A dosage form according to claim 1, wherein the high solubility active ingredient is selected from the group comprising of metformin hydrochloride, phenformin, buformin, captopril, ranitidine hydrochloride, potassium chloride, clindamycin, hydroxyurea, erythromycin lactobionate, vancomycin hydrochloride, balsalazide disodium, aminocaproic acid, lisinopril, tramadol, acetaminophen, ciprofloxacin, esters of ampicillin, sodium valproate, niacin, diltiazem, venlafaxine, isosorbide 5-imononitrate, isosorbide dinitrate, pentoxyphylline, propranolol and quetiapine or pharmaceutically acceptable salts thereof.

19. (original):A dosage form according to claim 1, wherein the dissolution of high solubility active ingredient is not more than 50% in 1 hour and from 25 to 90 % is released in six hours.

20. (original):A dosage form according to claim 1, wherein it reduces the chances of dose dumping, unnecessary burst effects and failure of the system.

21. (original):A dosage form according to claim 1 to 18, wherein the high solubility active ingredient is potent.

22. (original):A dosage form according to claim 21, wherein it reduces the chances of dose dumping, unnecessary burst effects and failure of the system.

23. (currently amended):A dosage form according to claim 21, where the high solubility potent active ingredient is selected from the group comprising of antidiabetic agents, anti-histamines, anti-depressants, anti-viral agents, anesthetics, antacids, anti-arththriics, antibiotics, anti-psychotics, anti-spasmodics, anxiolytic agents, appetite suppressants, cardiovascular agents, cough suppressants, emollients, gastro-intestinal agents, growth regulators, respiratory stimulants, vitamins, angiotensin converting enzyme inhibitors, anti-asthmatics, anti-cholesterolemics, anti-convulsants, anti-depressants, anti-diarrhea preparations, anti-infective, anti-inflammatory agents, anti-nauseants, anti-stroke agents, anti-tumor drugs, anti-tussives, anti-uricemic drugs, amino-acid preparations, antiemetics, antiobesity drugs, antiparasitics, antipyretics, appetite stimulants, celebral dilators, chelating agents, cholecystokinin antagonists, cognition activators, deodorants, dermatological agents, diuretics, erythropoietic drugs, fertility agents, synthetic hormones, laxatives, mineral supplements, neuroleptics, neuromuscular agents, peripheral vaso-dilators, prostaglandins, vaginal preparations, vaso-constrictors, vertigo agents,

biguanides, sulphonylurease, meglitinides, PPAR gama agonist
+insulin sensitisers (thiazolidinedione)+ and alpha-glucosidase inhibitors.

24. (original):A dosage form according to claim 21, wherein the high solubility potent active ingredient is selected from the group comprising of benzotropine mesylate, distigmine bromide, flupenthixol dihydrochloride, formotexol fumerate,glycopynolete,granisetron hydrochloride, bisoprolol fumerate, atropine sulphate, azatadine maleate, carteolol HCl, bromphenaramine maleate, nicotine, oxybutamine chloride, perinodopril erbumine, pilocorpine, poldine methyl sulfate and zalcitane.

25. (original):A dosage form according to claim 1, can be given twice a day or more preferably can be given once a day.

26. (original):A dosage form according to claim 1, is used for human beings.

27. (original):A dosage form according to claim 1, wherein the high solubility active ingredient is niacin.

28. (original):A modified release dosage form according to claim 1, wherein the composition of the micromatrix particles and coated micromatrix particles is as follows-

Micro matrix particles-

Niacin	75%w/w to 99%w/w
Eudragit RS	1%w/w to 25%w/w
Coated micro matrix particles	
Micro matrix particles	70%w/w to 99%w/w
Hydrogenated castor oil	1%w/w to 30%w/w
Magnesium stearate	0%w/w to 2%w/w

29. (original):A dosage form according to claim 1, wherein the high solubility active ingredient is sodium valproate.

30. (original):A process for the preparation of a modified release dosage form comprising a) preparing a micro matrix particles containing high solubility active ingredient and one or more hydrophobic release controlling agent and b) coating the said micromatrix particles containing high solubility active ingredient and one or more hydrophobic release controlling agent.

31. (original):A modified release dosage form comprising of a metformin hydrochloride prepared by using dual retard technique to control the release of metformin, said dosage form comprising a) micro matrix particles containing metformin hydrochloride and one or more hydrophobic release controlling agent and b) coating of one or more hydrophobic release controlling agent on micro matrix particles.

32. (original):A dosage form as claimed in claim 31, is in the form of tablet.

33. (original):A dosage form according to claim 31, wherein the hydrophobic release controlling agents employed for the micro matrix particles are selected from the group comprising of ammonio methacrylate copolymers type A and B as described in USP, methacrylic acid copolymer type A, B and C as described in USP, polyacrylate dispersion 30% as described in Ph. Eur., polyvinyl acetate dispersion, ethylcellulose, cellulose acetate, cellulose propionate (lower, medium or higher molecular weight), cellulose acetate propionate, cellulose acetate butyrate, cellulose acetate phthalate, cellulose triacetate, poly(methyl methacrylate), poly(ethyl methacrylate), poly(butyl methacrylate), poly(isobutyl methacrylate), poly (hexyl methacrylate), poly(isodecyl methacrylate), poly (lauryl methacrylate), poly(phenyl methacrylate), poly (methyl acrylate), poly (isopropyl acrylate), poly (isobutyl actylate), poly (octadecyl acrylate), waxes such as beeswax, carnauba wax, microcrystalline wax, and ozokerite; fatty alcohols such as cetostearyl alcohol, stearyl alcohol; cetyl alcohol and myristyl alcohol; and fatty acid esters such as glyceryl monostearate; glycerol monooleate, acetylated monoglycerides, tristearin, tripalmitin, cetyl esters wax, glyceryl palmitostearate, glyceryl behenate and hydrogenated castor oil.

34. (original):A dosage form according to claim 33, wherein the hydrophobic release controlling agents are selected preferably from ammonio methacrylate co-polymers.

35. (original):A dosage form according to claim 34, wherein the preferred from ammonio methacrylate co-polymers

preferably from Eudragit RS (Ammonio Methacrylate Copolymer type B USP), Eudragit RL (Ammonio Methacrylate Copolymer type A USP) and Eudragit NE30D (Polyacrylate dispersion 30% Ph. Eur.).

36. (original):A dosage form according to claim 31,wherein in micro matrix particles, metformin hydrochloride and one or more hydrophobic release controlling agents are present in a ratio of from 100:1 to 100:75.

37. (original):A dosage form according to claim 36,wherein in micro matrix particles, metformin hydrochloride and one or more hydrophobic release controlling agents are present preferably in a ratio of from 100:2.5 to 100:50.

38. (original):A dosage form according to claim 36, wherein in micro matrix particles, metformin hydrochloride and one or more hydrophobic release controlling agents are present more preferably in a ratio of from 100:2.5 to 100:30.

39. (original):A dosage form according to claim 36, wherein in micro matrix particles, metformin hydrochloride and one or more hydrophobic release controlling agents are present most preferably in a ratio of from 100:2.5 to 100:20.

40. (original):A dosage form according to claim 36 to 39, wherein in micro matrix particles, metformin hydrochloride can be less than or equal to 1500 mg.

41. (original):A dosage form according to claim 31, wherein the hydrophobic release controlling agents employed for coating the said micro matrix are selected from the group comprising ammonio methacrylate copolymers type A and B as described in USP, methacrylic acid copolymer type A, B and C as described in USP, polyacrylate dispersion 30% as described in Ph. Eur.,polyvinyl acetate dispersion, ethylcellulose, cellulose acetate, cellulose propionate (lower, medium or higher molecular weight), cellulose acetate propionate, cellulose acetate butyrate, cellulose acetate phthalate, cellulose triacetate, poly(methyl methacrylate), poly(ethyl methacrylate), poly(butyl methacrylate), poly(isobutyl methacrylate), poly (hexyl methacrylate), poly(isodecyl methacrylate), poly (lauryl methacrylate), poly(phenyl methacrylate), poly (methyl acrylate), poly (isopropyl acrylate), poly (isobutyl actylate), poly (octadecyl acrylate), waxes such as beeswax, carnauba wax, microcrystalline wax, and ozokerite; fatty alcohols such as cetostearyl alcohol, stearyl alcohol; cetyl alcohol and myristyl alcohol; and fatty acid esters such as glyceryl monostearate; glycerol monooleate, acetylated monoglycerides, tristearin, tripalmitin, cetyl esters wax, glyceryl palmitostearate, glyceryl behenate and hydrogenated castor oil.

42. (original):A dosage form according to claim 40, wherein the hydrophobic release controlling agents is selected from fatty acid esters.

43. (original):A dosage form according to claim 42, wherein the hydrophobic release controlling agents are

selected from the group comprising of hydrogenated castor oil and glycerol distearate.

44. (original):A dosage form according to claim 31, micro matrix particles and coating of one or more hydrophobic release controlling agents are present in a ratio of from 100:0.5 to 100:75.

45. (original):A dosage form according to claim 44, wherein micro matrix particles and coating of one or more hydrophobic release controlling agents are preferably present in a ratio of from 100:1 to 100:50.

46. (original):A dosage form according to claim 44, wherein micro matrix particles and coating of one or more hydrophobic release controlling agents are more preferably present in a ratio of from 100:2.5 to 100:20.

47. (original): A modified release dosage form according to claim 31, wherein the composition of the micromatrix particles and coated micromatrix particles is as follows-

Micro matrix particles-

Metformin hydrochloride	75%w/w to 99%w/w
Eudragit RS	1%w/w to 25%w/w

Coated micro matrix particles

Micro matrix particles	70%w/w to 99%w/w
Hydrogenated castor oil	1%w/w to 30%w/w

Magnesium stearate 0%w/w to 2%w/w

48. (original): A dosage form according to claim 31, wherein the dissolution of metformin hydrochloride is not more than 50% in 1 hour, from 30 to 90 % in four hours and not less than 65 % in twelve hours.

49. (original): A dosage form according to claim 31, is once a day oral formulation.

50. (original): A dosage form according to claim 31, is used for human beings.

51. (original): A dosage form according to claim 31, wherein the maximum plasma metformin concentration is achieved between 700 ng/ml and 2500 ng/ml.

52. (original): A dosage form according to claim 51, wherein the maximum plasma metformin concentration is achieved preferably between 900 ng/ml and 2400 ng/ml.

53. (original): A dosage form according to claim 51, wherein the maximum plasma metformin concentration is achieved more preferably between 1000 ng/ml and 2350 ng/ml.

54. (original): A dosage form according to claim 31, wherein the modified release metformin formulation for once daily administration exhibit invivo mean dissolution time (MDT) of approximately 4 hours to 6 hours.

55. (original): A dosage form according to claim 31, wherein the minimum plasma metformin concentration (at 24 hours)

ranges between 0 and 450 ng/ml after oral administration.

56. (original): A dosage form as claimed in claim 1, wherein the said dosage form is used to increase the payload of high solubility active ingredient.

57. (original): A dosage form as claimed in claim 31, wherein the said dosage form is used to increase the payload of metformin hydrochloride.

58. (original): A dosage form as claimed in claim 1, wherein the said dosage form may optionally contain more than one high solubility active ingredient.

59. (original): A dosage form as claimed in claim 31, wherein the said dosage form may optionally contain more than one antidiabetic active ingredient.

60. (original): A process for the preparation of a modified release dosage form comprising a) preparing a micro matrix particles containing metformin hydrochloride and one or more hydrophobic release controlling agent and b) coating the said micro matrix particles containing metformin hydrochloride and one or more hydrophobic release controlling agent.